K071423

EXECUTIVE SUMMARY - **Medline Latex Foley Catheter**

JUL 18 2007

Device Description

A Foley catheter is needed when normal urination is disrupted or it is necessary to keep track of urine production. The catheter is threaded through the urinary duct (urethra) and into the bladder. It is secured by means of a balloon at the tip which is inflated with sterile water after insertion. The Medline Latex Foley Catheter offers 3 different balloon sizes (3cc, 5cc, 30cc) and a wide range of catheter sizes to accommodate pediatric and adult applications (refer to table below). The relative size of the Foley catheter is described using French units (Fr). 1 Fr is equivalent to 0.33 mm or .013".

Catheter type	Balloon capacity	Size (Fr)	Item Number
2-way standard	3cc	6	DYND11706
2-way standard	3cc	8	DYND11708
2-way standard	3cc	10	DYND11710
2-way standard	5cc	12	DYND11752
2-way standard	5cc	14	DYND11754
2-way standard	5cc	16	DYND11756
2-way standard	5cc	18	DYND11758
2-way standard	5cc	20	DYND11760
2-way standard	5cc	22	DYND11762
2-way standard	5cc	24	DYND11764
2-way standard	5cc	26	DYND11766
2-way standard	5cc	28	DYND11768
2-way standard	5cc	30	DYND11770
2-way coude tip	5cc	14	DYND11214
2-way coude tip	5cc	16	DYND11216
2-way coude tip	5cc	18	DYND11218
2-way coude tip	5cc	20	DYND11220
2-way coude tip	5cc	22	DYND11222
2-way coude tip	5cc	24	DYND11224
2-way standard	30cc	12	DYND11772
2-way standard	30cc	14	DYND11774
2-way standard	30cc	16	DYND11776
2-way standard	30cc	18	DYND11778
2-way standard	30cc	20	DYND11780
2-way standard	30cc	22	DYND11782
2-way standard	30cc	24	DYND11784
2-way standard	30cc	26	DYND11786
2-way standard	30cc	28	DYND11788
2-way standard	30cc	30	DYND11790
3-way standard	30cc	16	DYND11800
3-way standard	30cc	18	DYND11801
3-way standard	30cc	20	DYND11802
3-way standard	30cc	22	DYND11803
3-way standard	30cc	24	DYND11804
3-way standard	30cc	26	DYND11805

The Medline Latex Foley Catheter is a flexible tubular device manufactured from natural high grade latex. For a listing of all the raw materials used, refer to attachment 2. It is sterile as packaged and intended for single patient use. The Medline Latex Foley Catheter consists of two types (2-way & 3-way) of devices. These catheters constitute a double or triple lumen drainage tube with two opposing eyelets on the proximal tip. On the other end of the catheter shaft, the urine drains out into an appropriate collection device. The 3-way catheter has an additional set of eyelets for irrigation purposes.

A silicon elastomer coating is applied to the catheter through a dipping process.

The catheters are supplied in individually packaged, sealed single use poaches.
Packaging Materials: Paper/Poly/Mylar film
Sealing Method: Heat sealed

Substantial Equivalence

Feature	Proposed Device	Predicate Device
Name	Medline Latex Foley Catheter	Foleycath NR Latex Balloon Catheter (K903777)
Intended Use	The Medline Latex Foley Catheter is intended to be used as a urological catheter inserted through the urethra for the purpose of draining urine and other fluids from the urinary tract.	The Foleycath is intended to be used for the drainage of urine and other fluids from the urinary bladder.
Patient Populations	Male, Female & Pediatric	Male, Female & Pediatric
Types	• 2-way • 3-way	• 2-way • 3-way
Size Range (Fr)	• Pediatric (6-10) • Female / Male (12-30)	• Pediatric (6-10) • Female / Male (12-30)
Balloon Capacity	3cc, 5cc, 30cc	3cc, 5cc, 30cc
Material	Natural rubber latex	Natural rubber latex
Coating	Silicone	Silicone
Labeling	See attachment 1	See attachment 1

Discussion of similarities and differences:

The proposed Medline Latex Foley Catheter is identical in intended uses, function and mode of operation to the predicate device which received marketing approval under K903777.

There are no significant differences between the two products. As reflected in the table above, they include identical product lines which support the same patient populations. They are fabricated from the same materials and designed in a same fashion.

Biocompatibility / Sterilization

Per the Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s, August 12,2005, section 15 – "If identical materials are used in a predicate with the same type and duration of patient contact, you may identify the predicate in lieu of performing biocompatibility testing and state that your device is comprised of identical materials and that are processed by identical manufacturing methods."

As noted, this device is identical to that of WRP Foleycath (K903777). The manufacturing and sterilization methods remain unchanged. The history of the biocompatibility of these products is therefore well established.

The product is sterilized by a Gamma Irradiation method. Refer to attachment 2 for details of this process.

Summary of Performance Testing

The Medline Latex Foley Catheter referenced in this submission is held to the same design, manufacture, and performance specifications as the currently marketed predicate device (K903777). The predicate device was tested in accordance with relevant standards for performance and function.

Product Labeling

The labeling, dimensional drawings & promotional materials for this device can be found in Attachment 1.

Conclusions

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Latex Foley Catheter is safe, effective and substantially equivalent as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 18 2007

Mr. Matt Clausen
Regulatory Affairs
Medline Industries, Inc.
One Medline Place
MUNDELEIN IL 60060-4486

Re: K071423
Trade/Device Name: Medline Latex Foley Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: May 18, 2007
Received: May 25, 2007

Dear Mr. Clausen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071423

Device Name: Medline Latex Foley Catheter

Indications for Use:

The Medline Latex Foley Catheter is intended to be used as a urological catheter inserted through the urethra for the purpose of draining urine and other fluids from the urinary tract.

Precautions:

Do not use petroleum based ointments or lubricants.

Contraindications:

Those individuals with a known sensitivity or allergy to latex are excluded from the use of this device. Product use should be discontinued should signs of sensitization occur.

Prescription Use _XX____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071423